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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/313,828	05/18/1999	JOHN R. LAU	23119/04016	4354

24024 7590 01/09/2003

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 01/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/313,828

Applicant(s)

Lau

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 10, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above, claim(s) 1-4, 6, 29, 31, and 37-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 7-28, 30, and 32-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The response dated 4-10-02 and the revocation of power of attorney dated 11-13-02 are acknowledged.

Claims included in the prosecution are 5, 7-28, 30 and 32-36.

Claim Objections

Claims 5, 7-11 are objected to since they depend from non-elected claims. These claims are being examined since they are product claims, though dependent on the process claims.

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 5, 7-28, 30 and 32-36 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 88/00474 of record or Geho (4,603,044) also of record.

WO 88 and 044 both disclose liposomes containing either Cr, Co, Fe or Zn complexed with imunodiacetic acid derivatives. The liposomes further contain either

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insulin or serotonin. (Note abstract, pages 9-16, 22-28 and claims; abstract, columns 2-22 and claims in 044).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments mostly relate the differences in the method of production and not based on how the instant product is different from the prior art product. Therefore, the rejection is maintained.

3. Claims 5, 13, 22, 24, 32-33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Bosworth (5,407,660) of record.

Bosworth discloses liposomes containing chelates of iron for diagnostic applications. The liposomes contain cholesterol (note the abstract, Examples and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Bosworth's compounds are water soluble whereas instant compounds are water insoluble. This argument is not found to be persuasive since claims do not reflect this parameter; instant independent claims do not recite any specific compound. Furthermore, liposomes made from phospholipid are water insoluble and in fact, Bosworth in examples refers to the complexes as suspensions. In essence, the differences argued by applicant are not reflected in the claims. With regard to applicant's arguments that Bosworth's liposomes are not directed to hepatocytes:- the examiner points out that instant claims are composition claims and intended use has no significance.

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Furthermore, the feature (component) which makes the complex react only with hepatocytes is not recited in the claims.

4. Claims 5, 13, 1518, 22, 24, and 32-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Baldeschwieler (4,310,506) of record.

Baldeschwieler discloses liposomes containing chelates of metals such as Cr, In, Co, Zn with iminodiacetic acid for diagnostic applications. The liposomes contain distearoylphosphatidylcholine, dicetyl phosphate and cholesterol (note the abstract, columns 2-4, Examples and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments are similar to those put forward for the rejection over Bosworth and hence same response is applicable. Applicant's arguments that although the Baldeschwieler invention and the present invention describe the use of chromium, there is a critical difference in the use of chromium are not found to be persuasive since these are composition claims and the way chromium is use has no significance in composition claims.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant's request for an interview is noted. An interview will be granted after applicant reviews the office action and proposes an amendment if necessary.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

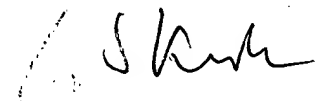
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

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All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk